

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 9-11 are pending.

Claim for Priority Benefit

Applicants disagree with the Examiner's allegation on page 2 of the Action that their argument was not persuasive. The pending claims are directed to the treatment of uveitis, which is an autoimmune disease. The priority application provides detailed and complete support for autoimmune diseases and gives some specific examples of such diseases: multiple sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Uveitis is another autoimmune disease that was included in the disclosure of Int'l Appln. No. PCT/IT03/00237, which claimed priority benefit of parent Appln. No. 10/137,699. Therefore, the invention being examined in this application is directed to another specific embodiment of the parent application and priority benefit should be granted.

In general, there is no need to provide literal support in a parent application for a subsequent example of carrying out the invention that is claimed in a child application. In the parent application, the generic concept of "autoimmune disease" was embodied in three different examples: multiple sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Applicants submit that such support puts them in possession of treatment of other autoimmune diseases. Furthermore, there is no evidence of record that such support does not put Applicants in possession of the invention claimed in this application. Therefore, the claim of priority benefit is proper for a further example of the same invention.

In the Action mailed November 29, 2006, the Examiner stated that Applicants' arguments were not deemed persuasive. He did not, however, provide any reason for disagreeing with the facts and conclusions presented on July 17, 2006. Absent a basis for not being persuaded by Applicants' arguments, it is submitted that the Examiner's decision is improper under the Administrative Procedure Act. His reconsideration of the decision is requested and, if not successful, reasons for denial are requested.

Acknowledgment is requested that Applicants' claim of priority benefit is proper.

35 U.S.C. 112 – Definiteness

Claims 9-11 were rejected under Section 112, second paragraph, as being allegedly “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Applicants traverse.

The phrase “effective amount” is deleted from claim 9. Although it is Applicants’ belief that such language is not confusing as alleged in the Action, this limitation is not required for patentability so its deletion should overcome this rejection.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 9-10 were rejected under Section 102(b) as allegedly anticipated by Mistrello et al. Applicants traverse. It is noted that the cited reference was a basis for rejecting the claims in the parent U.S. Patent 6,797,722, but this rejection was overcome in allowing the claims.

Claim 1 of the ‘722 patent is directed to the treatment of autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus, and rheumatoid arthritis with the same compound as the claims in this application. In consideration of novelty, Applicants submit that multiple sclerosis, systemic lupus erythematosus, rheumatoid arthritis, and uveitis all belong to the genus of autoimmune diseases, but each one is a different disease. One species of the genus cannot anticipate a different species of the same genus. *Cats and dogs are both mammals, but a cat is different from a dog and vice versa. In analogy to the case of genus-species, a cat cannot anticipate a dog.* Anticipation requires “each and every limitation” to be taught in the reference. The treatment of

polyarthritis does not teach uveitis. Although both are autoimmune diseases, a specific autoimmune disease (e.g., polyarthritis) does not teach a different autoimmune disease (e.g., uveitis).

Applicants respectfully request withdrawal of the Section 102 based on the arguments presented above and of record in this application, and in view of U.S. patent law and the Patent Office's practice.

35 U.S.C. 103 – Nonobviousness

To establish a case of *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992).

Claim 11 was rejected under Section 103(a) as allegedly unpatentable over Mistrello et al. in view of Mozes et al. Applicants traverse. The Patent Office's guidelines for determining obviousness in genus-species situations are found at M.P.E.P. 2144.08.

In Mistrello et al., the compound was unsuccessful in treating arthritis. One of ordinary skill in the art, when carefully reading the reference will find the compound's immunosuppressive profile and its use in the treatment of heterologous skin transplantation disclosed. But the rejection of such transplants is not an autoimmune disease. In this reference, the compound is clearly ineffective in treating arthritis. The uses for the ST1959 compound disclosed in this reference are not sufficient to establish that it is effective in treating any autoimmune disease, especially uveitis. Therefore, there is no reasonable expectation of success provided in Mistrello et al. or in the other evidence of record. But a determination of *prima facie* obviousness requires a reasonable expectation of success. See *In re Rhinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976). Moreover, the requirements of M.P.E.P. 2144.08 are not satisfied for establishing a case of *prima facie* obviousness in accordance with the guidelines for the examination of claims

directed to a species when the reference discloses the genus. Here, Mistrello et al. fail to disclose successful treatment of any autoimmune disease.

The disclosure of Mozes et al. does not remedy the failure of Mistrello et al. to establish a reasonable expectation of success in using the ST1959 compound in the treatment of any autoimmune disease, especially uveitis. It was admitted on page 5 of the Action that neither Mistrello et al. nor Mozes et al. teach uveitis. Therefore, a *prima facie* case of obviousness is not established if all claim limitations fail to be taught or suggested by the prior art in accordance with M.P.E.P. 2143.03.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to one of ordinary skill in the art at the time it was made.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:

Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100